K091338

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510(k) Summary
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name: HARTMANN-CONCO Inc.

Company Address: 481 Lakeshore Parkway
Rock Hill, SC 29730

AUG 2 6 2009

Telephone: 803-325-7600
Fax: 803-325-7606

Contact Person: Scott Cost

Summary Preparation Date: March 2, 2009

DEVICE NAME **807.92(a)(2)**

Trade Name:	CollaSorb™ Collagen Wound Dressing
Common/Usual Name:	Collagen Wound Dressing
Classification Name:	Dressing, Wound, Collagen
Regulation Number:	Unclassified
Product Code:	KGN
Device Class:	Unclassified

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Covalon Technologies, Inc.	Colactive Collagen Wound Dressing	K050177

DEVICE DESCRIPTION **807.92(a)(4)**

CollaSorb™ wound dressing is a wound care product composed of a native collagen and calcium-alginate, which comes as a sterile, non-pyrogenic product for single use in a single pouch package.

CollaSorb™ wound dressings are pliable, absorbent dressings that absorb moisture such as wound fluid by forming a soft, conformable moist gel sheet at the wound surface and thus maintaining a moist environment. Due to its excellent wet stability and elasticity the CollaSorb™ wound dressing can easily be applied and fitted to the wounds and is also for the management of deep wounds.

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DEVICE INTENDED USE 807.92(a)(5)

CollaSorb™ Collagen Wound Dressing is indicated for the management of full and partial thickness wounds including:

- Pressure ulcers
- Diabetic ulcers
- Ulcers caused by mixed vascular etiologies
- Venous ulcers
- Second degree burns
- Donor and graft sites
- Abrasions
- Dehisced surgical wounds
- Traumatic wounds healing by secondary intention

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Device Name	CollaSorb™	ColActive™
Indications for use	- Pressure ulcers - Venous ulcers - Diabetic ulcers - Ulcers caused by mixed vascular etiologies - Second degree burns - Donor and graft sites - Abrasions - Dehisced surgical wounds - Traumatic wounds healing by secondary intention	- Pressure ulcers - Venous ulcers - Diabetic ulcers - Ulcers caused by mixed vascular etiologies - Second degree burns - Donor and graft sites - Abrasions - Dehisced surgical wounds - Traumatic wounds healing by secondary intention
Material	Collagen / Calcium-Alginate	Collagen / Sodium-Alginate
Biodegradable	Yes	Yes
Biocompatibility	In accordance with ISO 10993-1	In accordance with ISO 10993-1
Non-Pyrogenic	Yes (rabbit pyrogen test)	-
Sterile	Yes – gamma radiation	Yes – gamma radiation
Size	2 in x 2 in (5 cm x 5 cm = 25 cm^2) 4 in x 4 in (10 cm x 10 cm = 100 cm^2)	2 in x 2 in (5 cm x 5 cm = 25 cm^2) 4 in x 4 in (10 cm x 10 cm = 100 cm^2)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 2 6 2009

Hartman-Conco Inc.
% Smith Associates
Mr. E.J. Smith
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K091338
Trade/Device Name: CollaSorb Collagen Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: August 3, 2009
Received: August 5, 2009

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091338

Indications for Use

510(k) Number (if known): _____

Device Name: CollaSorb Collagen Wound Dressing

Indications for Use:

CollaSorb™ Collagen Wound Dressing is indicated for the management of full and partial thickness wounds including:

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- Abrasions
- Dehisced surgical wounds
- Traumatic wounds healing by secondary intention

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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